

Dakai Liu and Elazar Rabbani

Serial No. 09/046,833

Filed: March 24, 1998

Page 3 [Amendment Under 37 C.F.R. §1.116 (In Response To The May 26, 1999

Office Action) - April 5, 2000]



REMARKS

Reconsideration of this application is respectfully requested.

Claims 68-74 were previously pending and are also being presented once again in this Amendment. Claim 68 has been amended above. No other claims have been amended, added or canceled by this paper.

Two minor informalities on pages 13 and 14 have been corrected in the specification. Information regarding the serial number for the U.S. patent application referenced on page 21 in the specification has also been inserted.

The main independent claim, 68, has been amended to recite that the nucleic acid component and the non-nucleic acid component are "capable of forming a specific localized complex." Support for the foregoing amendment is drawn from the specification, page 6.

The Rejection Under 35 U.S.C. §102(b)

Claims 68-74 stand rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Salmons et al. ["Targeting of Retroviral Vectors for Gene Therapy," Human Gene Therapy 4:129-141 (1993)] or Smith et al. ["Viral Vectors in Gene Therapy," Ann. Rev. Microbiol. 49:807-818 (1995)]. In the Office Action (pages 2-3), the Examiner stated:

This rejection is maintained for reasons of record in the previous Office Action (Paper # 4) and for reasons outlined below. The rejection is expanded to include new claims 69-74 as a result of applicants' amendment filed 3/10/99.

Applicants traverse this rejection by asserting that the amended claim 68 and new claims 69-74 (which depend from claim 68) are not taught by Salmons et al. or Smith because neither reference teaches the claimed feature wherein the nucleic acid component and the non-nucleic acid component are capable of forming a specific complex with each other. Applicants subsequently argue that the useful properties of the invention as now claimed involve localization to defined regions of a nucleic acid construct, reduction or elimination of potential interference with region segments in the nucleic acid constructs, etc.

Filed: March 24, 1998

Page 4 [Amendment Under 37 C.F.R. §1.116 (In Response To The May 26, 1999
Office Action) - April 5, 2000]

Applicants' remarks filed 3/10/99 have been carefully considered but are not deemed persuasive. First, the newly added limitation concerning "...said nucleic acid component and said non-nucleic acid component being capable of forming a specific complex..." reads on a nucleic acid component of a vector and a protein component of a viral vector particle, i.e. a retroviral vector nucleic acid molecule and a gag, env or pol protein molecule. Given this reading of the claim language, Salmons et al. and Smith both recite packaging cell lines which comprise a viral (retroviral) vector comprising a nucleic acid component and a non-nucleic acid component (i.e. gag, env or pol) being capable of forming a specific complex with each other in the context of a viral vector particle.

Second, with regard to newly added claims 69-74, both Salmons et al. and Smith teach retroviral vector packaging cell lines which can be derived from cells "native" to the viral vector, i.e. Ψ -2 cells or Ψ -am or PA317 etc. cells and wherein the viral vector nucleic acid component can be native or non-native (i.e. having endogenous or heterologous expression control sequences, etc.) to the vector and wherein the viral vector nucleic acid component consists of genomic viral DNA (i.e. provirus) or fragments of said DNA. With regard to the packaging cell expressing on its membrane a member which can be a non-native viral vector nucleic acid component, etc., it is noted that both Salmons et al. and Smith teach the construction of pseudotyped retroviral vectors wherein the packaging cells express on their membrane a non-native viral vector nucleic acid component. Therefore, Salmons et al. and Smith both teach the claimed invention.

The anticipation rejection is respectfully traversed.

As indicated in the opening remarks above, claim 68 has been amended to recite that the nucleic acid component and the non-nucleic acid component are "capable of forming a specific localized complex." As set forth in Applicants' previous response, it is believed that neither of the cited documents disclose nucleic acid components and non-nucleic acid components capable of forming a specific complex, let alone a *localized* specific complex. Salmons et al. and Smith disclose non-nucleic acid components, such as gag, env and pol, but these do not form nor are they capable of forming Applicants' claimed localized specific complex, as defined in the present claims and described in their disclosure. Thus, claim 68 as it now reads should be deemed patentable and not anticipated by the cited documents.

Because claim 68 is patentable and not anticipated by Salmons et al. or Smith, claims 69-74 that depend from claim 68 must likewise be deemed patentable and not anticipated.

In view of the above amendment to claim 68 and the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the anticipation rejection.

The Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 68-74 stand rejected for alleged indefiniteness under 35 U.S.C. §112, second paragraph. In the Office Action (page 4) the Examiner stated:

Claim 68 (and dependent claims) is vague in the recitation of the phrase "capable of forming a specific complex" since the capacity of a compound or composition to perform some function is merely a recitation of a latent characteristic of said composition or compound and said language carries no patentable weight, i.e. it is unclear under what conditions the compounds can form a specific complex and under what conditions they cannot.

Claims 71-73 are vague with regard to the viral vector nucleic acid being native or non-native to the vector. Since the claimed viral vectors can be composed of components from two or more sources, language reading on components "native" or "non-native" to the vector has no meaning since the context of the terms "native" or "non-native" is unclear.

The indefiniteness rejection is respectfully traversed.

With respect to the language "capable of forming a specific (localized) complex," it is believed that this recitation is proper and meets the statutory strictures for definiteness. Without having conducted an extensive search of the patent literature, the present Assignee can point to one of its own issued U.S. patents as evidence of the claim worthiness of the phrase at hand. In U.S. Patent No. 4,746,604, issued on May 24, 1988, claim 7 recites:

An assay method for detecting an analyte in a sample, which method comprises the steps of:

- a. affixing said sample suspected of containing said analyte to a solid support;
- b. combining said affixed analyte with a composition comprising (i) an analyte specific component **capable of forming a specific complex** with said analyte and (ii) a detectable component comprising an organism selected from the group consisting of microorganisms, fungal cells, plant cells and animal cells capable of

growth or reproduction, which detectable component has been attached to said analyte specific component to form a resultant complex;

c. separating non-complexed detectable component from said complex; and

d. placing said complex in an appropriate environment to encourage growth or reproduction of said detectable component, wherein growth or replication is proportional to analyte concentration.

[emphasis added]

A copy of U.S. Patent No. 4,746,604 is attached to this Amendment as Exhibit 1.

Applicants respectfully maintain that the aforementioned language is clear in its meaning and commensurate in scope with their disclosure. Moreover, it is submitted that the recitation at hand defines Applicants' present invention so as to distinguish over the cited Salmons and Smith documents. Accordingly, the phrase "capable of forming a localized complex" passes muster under the statutory standard for claim definiteness.

With respect to the "native" and "non-native" components recited in any of the claims, it is believed that this terminology is proper and definite. Claim 71 recites that "said viral vector nucleic acid component is native to said vector." Claim 72 recites that "said viral vector nucleic acid component is non-native to said vector." Claim 73 depends from claim 72 and recites as Markush members "a receptor for said non-native viral vector nucleic acid component, a binding partner for said non-native viral vector nucleic acid component, and an adsorption partner to said non-native viral vector nucleic acid component." A person skilled in the art would appreciate not only the meaning but the metes and bounds of the subject matter embraced by the terms "native" and "non-native" as set forth in claim 71-73.

In view of the foregoing remarks and attached Exhibit 1, it is believed that the definiteness rejection has been obviated. Applicants respectfully request, therefore, reconsideration and withdrawal of the rejection.

Sequence Listing Requirement

In the Office Action (pages 4-5), the Examiner stated:

With regard to the Sequence Listing Requirement, it is noted that the Sequence Listing in the parent application (Serial No. 08/822,963) has not been submitted in an acceptable form and no Sequence Listing file for the 08/822,963 application exists. Since no file for the parent exists applicants must submit a Sequence Listing for the instant application. or if a suitable Sequence Listing is eventually filed in the parent application, applicants may rely upon that CRF to prepare a file for the offspring. Any response to this Office Action that does not address this issue will be considered non-responsive.

In response, Applicants wish to point out that a sequence listing was submitted on March 15, 1999 in connection with the parent application (Serial No. 08/822,963). This submission included an Amendment In Response To June 5, 1998 Office Action Directing Applicants To Comply With The Sequence Rules Under 37 C.F.R. §1.821-I.825 (which Amendment contained a computer readable form of the sequence listing and as well as a paper copy of the listing) and a Declaration Under 37 C.F.R. §1.821(g). A copy of that Amendment (including a paper copy of the sequence listing) and the Declaration is attached as Exhibit 2.

Applicants respectfully request that the computer readable form of the sequence listing in the parent case be used to prepare a file for this offspring application (Serial No. 09/046,841, filed March 24, 1998). Applicants, through their undersigned attorney, further states that the paper copy of the Sequence Listing in the parent application, accompanying this Amendment as Exhibit 2, is identical to the Sequence Listing in the instant application (Serial No. 09/046,841 filed March 24, 1998).

* * * * *

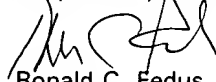
SUMMARY AND CONCLUSIONS

Claims 68-74 are presented for further examination. Only claim 68 has been amended. All other claims are unaffected by this Amendment.

No fee is deemed necessary in connection with the filing of this Response, other than the fees under sections 37 C.F.R. §1.17(r),(b), and (a), respectively, for filing of the accompanying Petition Under 37 C.F.R. §1.137(b) To Revive An Unintentionally Abandoned Application, the Terminal Disclaimer, and the Notice Of Appeal To The Board Of Patent Appeals And Interferences. If any other fee or fees are due, however, for this response or the accompanying filings, The Patent and Trademark is authorized to charge the amount of any such fee(s) to Deposit Account No. 05-1135, and to credit any overpayment thereto.

Applicants respectfully submit that all of the instant claims are in allowable condition. Should it be deemed helpful or necessary, the Examiner is respectfully invited to telephone the undersigned at (212) 583-0100 to discuss the subject application.

Respectfully submitted,



Ronald C. Fedus
Registration No. 32,567
Attorney for Applicants

ENZO THERAPEUTICS, INC.
c/o Enzo Biochem, Inc.
527 Madison Avenue, 9th Floor
New York, New York 10017
Tel.: (212) 583-0100
Fax.: (212) 583-0150

lc\uspros\enzz56(D4)\AmendmentEnz56(D4).040500